June 25, 1998

**SUBJECT:** Sulfosate (PC #128501; CAS Registry #81591-81-3)
ICIA0224 (ZENECA)
ID #010182-00322
DP BARCODE D244127 (Submission #S539017):
Review of Protocol for an Aquatic Field Dissipation Study (164-2)

DP BARCODE D246815 (Submission #S544164):
Response to ZENECA's Questions about the Design of their Aquatic Field Dissipation and rationale for submitting an Aerobic Aquatic Metabolism Study performed following SETAC and BBA Guidelines

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An **Aerobic Aquatic Metabolism (162-4)** and an **Aquatic Field Dissipation (164-2)** will be submitted by ZENECA to support registration of sulfosate for **uses on rice.**

On 02/23/98, ZENECA submitted a protocol for Aquatic Field Dissipation studies. On 05/13/98, ZENECA submitted a letter asking specific questions about an existing Aerobic Aquatic Metabolism study conducted towards reregistration of sulfosate in the European Union and if the study could be used towards registration of sulfosate for rice aqua-culture in the United States. In the same letter, ZENECA requested responses to questions related to the protocol for the Aquatic Field Dissipation study.

## I. CONCLUSIONS

1. ZENECA may submit the already available Aerobic Aquatic Metabolism, but attention should be paid to EFED's comments and recommendations in Part A.

2. The proposed protocol for aquatic dissipation studies was reviewed. ZENECA must consider carefully EFED's comments and recommendations in Part B.

3. In a separate communication to RD, EFED will address ZENECA's rationale for using the aquatic field dissipation studies in California and Mississippi to support registration for use of sulfosate in wild-rice culture in Minnesota.

4. It is not clear why a metabolite representing 11-14% in the water of the aerobic aquatic metabolism study was not identified. Therefore, no recommendation can be made whether this metabolite should be analyzed in the field study until yhis is done. Further information is needed. From analytical work performed for studies involving soils and sediments (anaerobic aquatic metabolism), is there a common characteristic (for instance, extraction and chromatographic behavior) that maybe used to infer the chemical nature of the unidentified metabolite?

Other Information

1. The terrestrial field dissipation study(ies)submitted by ZENECA have been sent to the contractor for review.

2. The analytical methods (soil and water matrices) have been submitted for validation at the USEPA Environmental Chemistry Laboratory in Bay St.Louis.

## II. SPECIFIC COMMENTS

A. *Response to Questions Related to the Aerobic Aquatic Metabolism Study Already Conducted by ZENECA to Support Reregistration in the European Union:*

Submission of this study is acceptable. This study was conducted under SETAC Guideline 8.2 and BBA Part IV guidelines for European Union reregistration.

The following information, if available, should be included in the submission either within the report or as a separate document:

1. Indicate where the water/sediment systems were collected.

2. Indicate if any of these sediments were used in the batch-equilibrium adsorption/desorption studies or, in the case they were not, how do they compare to the soils/sediments used in the 163-1 study. Also discuss how the water/sediment system used in the 162-4 study compare to water/sediment-soils in rice aqua-culture sites in the USA.

3. Data on chemical characterization of water, including metal content profile and/or any characterization of suspended colloidal matter.

4. Sediment characterization, including mineralogy (if available).

5. Report pH, dissolved oxygen concentration and redox potential if measured and recorded at selected times during the study and/or continuously monitored.

6. Indicate why the metabolite at 11-14% was not identified and discuss potential transformation products.

7. Report DT50s and half-lives. If transformation/dissipation under aerobic conditions is "biphasic", include both the primary and secondary half-lives and DT50s. If possible, include rate constants.

8. Besides percent of the applied radioactivity include concentration of parent and degradates in mg/kg of sediment, mg/L (water phase) as well as ppm. The amount of degradation products should be presented separately for the water and sediments phases.

9. Include the patterns of formation and decline of transformation products and, when feasible, include their rates of formation and decline.

10. Compare the results of the aquatic metabolism studies (aerobic versus anaerobic) in terms of degradation/dissipation rates, transformation products and transformation/dissipation pathways. Were the same water/sediment systems used in the anaerobic aquatic metabolism study(ies)?

11. It was noted that the decline in mass balance was attributed to incomplete trapping of $^{14}CO_2$ or to transient low-molecular weight products, as well as $^{14}CO_2$ solvated in water. It was also noted that there is and steady increase of "carbonate" in the aqueous phase. How was "carbonate" analyzed? Was any consideration given to the pH-dependent predominance of species in the $CO_2/HCO_3^-/CO_3^{2-}$ system?

B. *Review of Protocol for Aquatic Dissipation Studies (Guideline 164-2) and Response to ZENECA's Questions Related to this Study*

The sites for this study will be in rice-growing areas in California and Mississippi.

Page 2- Sample Receipt and Preparation
Handling of the sediment is described, but not for the water phase. On "(5)", it is indicated that the melted water from the sample will be discarded. the rationale for this step is unclear since measurable residues may be present in the discarded water.

Storage stability data should be included in the report and should address the effect of thawing the sediment samples on the nature and relative concentration of analytes.

Page 3- Data Analysis
It is presumed that data generated from this study will be analyzed separately for sediment and water. In addition of DT50s, half-lives should also be included. If necessary, primary and secondary dissipation kinetics should be included (DT50s, $t_{1/2}$s, rate constants).

Page 5- Site Selection- Soil Characterization
The routine soil characterization (texture, pH, CEC, moisture holding capacity) and methods used should be included.

In addition, the following should be reported for each site:
a. Soil Series Name, indicating how characteristic the soil is for rice aqua-culture;
b. Competing soil series within rice growing areas;

c. Clay mineralogy, if applicable;
d. Other mineral phases;
e. Metal profile.

Page 5- Test Substance
Local water diluent: Measure pH for each application, before and after flooding and at selected sampling times. Include the data in the report.

Page 6- Plot Details
In addition to the descripton of the study plots, the following should be included in the report:
a. Longitude and latitude, topology, vegetation, and target weeds at each site.
b. Monthly rainfall and temperature over a 50-year period.
c. Evapotranspiration data.
d. Weather conditions throughout the duration of the studies.
e. Time of planting and development of the crop.
f. Comparison of the soils in the selected sites with those used in laboratory studies (soil photolysis, soil metabolism, and batch-equilibrium adsorption/desorption studies).

Note: Consider the situation where very heavy rainfall events occur while the studies are in progress. This could cause over-flooding of the paddies and subsequent "run-off" and alter the course of the study. The registrant should be aware of this potential situation and be prepared in case that it is necessary to collect "run-off" samples.

Page 8- Sampling

1. *Deposition Samples, Page 8-*
Indicate the weight of the soil in each aluminum pan.
It is presumed that the soil was taken from the pre-flooded paddy.

2. *Water Sampling, Pages 8 and 9-*
a. Record and report *in-situ* temperature, dissolved oxygen concentration, and redox potential of flood water at each sampling time and at selected times between sampling.
b. Utilize a water sampling method that minimizes disturbing the sediment. For example, gentle withdrawal with a suction device as opposed to submerging a 500-mL bottle.

3. *Sediment and Soil Samples, Page 9(5)-*
It may be useful to compare turbidity before and after sediment removal to determine if sediment particles become suspended in solution.

Other- Residues (parent; degradation products) in soil and water should be expressed in $mg/kg_{dry\ soil}$ (soil) and mg/L (water), as well as in parts per million (ppm).